

January 20, 2017

VIA EMAIL

Dana Perez
Case Manager to Judge George C. Hanks, Jr.
United States Courthouse
601 Rosenberg, Room 411
Galveston, TX 77550
galveston_cm@txs.uscourts.gov

Re: Conference Regarding Discovery Motion in *Texas Dep’t Criminal Justice v. U.S. Food and Drug Administration, et al.*, Case No. 3:17-cv-00001

Dear Judge Hanks:

Counsel for the parties in the above-referenced case respectfully seek the Court’s assistance in resolving a dispute concerning the availability of discovery and privilege in this matter. Plaintiff’s counsel (Daniel G. Jarcho) and Defendants’ counsel (Alexander Sverdlov, Paige Taylor and Christine Kearsley) discussed the issue in an 11:00 a.m. teleconference on January 4, 2017 and have been unable to reach agreement. The parties therefore respectfully ask that the Court resolve the dispute following the submission of briefs, as permitted by the Federal Rules of Civil Procedure (FRCP). Pursuant to section 6.C.5 of this Court’s procedures, the parties request a conference with the Court to address Plaintiff’s intent to file a discovery motion. Because most of the counsel involved are in the Washington, D.C. area, counsel respectfully request the Court to conduct the conference by telephone.

Case Background

This case arises from a dispute between the Texas Department of Criminal Justice (TDCJ) and the U.S. Food and Drug Administration (FDA) over the importation of a shipment of the drug thiopental sodium. TDCJ is responsible for administering criminal sentences in Texas and has attempted to import the drug to carry out capital sentences through lethal injection. FDA is subject to a court order permanently enjoining the agency from permitting the entry of any shipment of foreign-manufactured thiopental that appears to be misbranded or an unapproved new drug. *See Beaty v. FDA*, 853 F. Supp. 2d 30 (D.D.C. 2012), *aff’d in part, rev’d in part sub nom. Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013). TDCJ maintains that the drugs in the shipment at issue are not misbranded or unapproved new drugs. The shipment was offered for importation in July 2015. In August 2015, FDA issued a “Notice of FDA Action” stating that the shipment was detained and subject to refusal of admission on certain specified bases. After reviewing TDCJ’s written response, FDA provided TDCJ with its tentative conclusions in April 2016, but FDA has not rendered a final decision on the legality of the importation. TDCJ alleges that FDA has unlawfully withheld or unreasonably delayed its final decision on the legality of the importation. TDCJ’s complaint seeks an injunction under the Administrative Procedure Act

January 20, 2017

Page 2

(“APA”), 5 U.S.C. § 706(1), compelling FDA to issue its final decision regarding admissibility of the import. TDCJ’s complaint also seeks a declaratory judgment that FDA has unlawfully delayed that final decision.

Plaintiff’s Position

Although the Court has issued an order directing the parties to develop a discovery plan, some APA cases are exempt from discovery requirements and adjudicated on an administrative record. *See FRCP 26(a)(1)(B)(i), 26(f)(1)*. The status of the existing discovery order is unclear, because TDCJ understands that Defendants believe this case is exempt from discovery. To clarify the parties’ course of conduct in this case, including whether a Rule 26(f) conference is applicable, the Court should make a threshold determination at this time that TDCJ is entitled to pursue discovery. TDCJ submits that discovery is available in an Administrative Procedure Act (APA) case challenging an agency’s failure to act. *See, e.g., Nat’l Law Center on Homelessness and Poverty v. U.S. Dept. of Veterans Affairs*, 842 F. Supp. 2d 127, 130-31 (D.D.C. 2012). TDCJ maintains that this case is not subject to restrictions on discovery that apply when a party challenges an affirmative agency action under the APA, because TDCJ challenges FDA’s *failure* to act. TDCJ also submits that to prevent collateral disputes between the parties, the Court should order that FDA is not entitled to invoke the deliberative process privilege in response to TDCJ’s discovery requests. When it applies, that privilege protects certain pre-decisional internal government communications. TDCJ maintains that the privilege does not apply where, as here, a plaintiff’s claim focuses on the agency decision-making process itself. *See, e.g., U.S. v. Lake County Bd. of Commissioners*, 233 F.R.D. 523, 526 (N.D. Ind. 2005).

Defendants’ Position

The United States maintains that TDCJ’s discovery request is inappropriate and premature. An unreasonable-delay claim is evaluated based on objective factors. *See Telecomm. Research & Action Ctr. v. FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984). Like in any other APA action, these factors should be evaluated based on the record produced by the agency. *See, e.g., Seattle Audubon Soc’y v. Norton*, No. C05-1835L, 2005 U.S. Dist. LEXIS 42243, at *9-11 (W.D. Wash. May 24, 2005) (using “the administrative record as the presumptive limitation of scope”). Moreover, FRCP 12(a)(2) affords Defendants until March 18, 2017 to file an answer or a motion to dismiss, and FRCP 26(d)(1) prohibits TDCJ from seeking discovery before the parties’ Rule 26(f) conference. This Court also should refuse to consider TDCJ’s attempt to preempt any assertion of the deliberative process privilege outside the context of a specific assertion of privilege in response to an actual discovery request. Plaintiff has not alleged that Defendants’ subjective motivation is at issue, and the privilege is intended “to protect the decision-making process from the inhibiting effect that disclosure of pre-decisional advisory opinions and recommendations might have on the ‘frank discussion of legal and policy matters’ in writing.” *May v. Dep’t of Air Force*, 777 F.2d 1012, 1014 (5th Cir. 1985) (citing *NLRB v. Sears*, 421 U.S. 132, 150 (1975)).

January 20, 2017
Page 3

Sincerely,

/s/ Daniel G. Jarcho
Daniel G. Jarcho, Attorney In Charge
Edward L. Marshall
Matthew Ottoway
Counsel for Plaintiff

JOYCE R. BRANDA
Acting Assistant Attorney General

MICHAEL S. BLUME
Director

ANDREW E. CLARK
Assistant Director

s/ Alexander V. Sverdlov
ALEXANDER V. SVERDLOV
Trial Attorney
Consumer Protection Branch
Civil Division
U.S. Department of Justice
P.O. Box 386
Ben Franklin Station
Washington, DC 20044
Tel: (202) 307-0138
Fax: (202) 514-8742

Attorneys for Defendants